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EXAMINER

GAMBEL, PHILLIP

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,067

Applicant(s)

PAGE ET AL.

Examiner

Phillip Gambel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/6/06; 11/27/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. 07/777,730.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's election of the Species where the human is afflicted with a T cell disorder / an autoimmune disease, and wherein the human is afflicted with arthritis in the Reply To Election Of Species Requirement, filed 11/6/06, is acknowledged.

During a telephone conversation with MaryAnne Armstrong on 11/27/06, a provisional election was made with traverse to prosecute the species of the two-part dosing regime, as the second species election set forth in the Restriction Requirement, mailed 10/4/06.

Affirmation of this election must be made by applicant in responding to this Office action.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-3, 7-10 as they read on the elected invention of arthritis are under consideration in the instant application.

Given the election of the two-part dosing regime, the species election has been extended to both species of dosing indicated in the Restriction Requirement, mailed 10/4/06, in the interest of compact prosecution.

Claims 4-6 have been withdrawn from consideration as being drawn to the non-elected invention.

2. Applicant's Information Disclosure Statement, filed 8/15/06, is acknowledged.

This Information Disclosure Statement has been crossed out, as it is a duplicate of the Information Disclosure Statement, filed 9/25/06 with the submission of the RCE.

Given applicant's reliance upon the submission of documents in parent application USSN 10/145,992,

the following is noted, as it was noted in parent application USSN 10/145,992.

The information disclosure statement, filed 8/15/2006, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the crossed-out information referred to therein has not been considered.

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In addition to the lack of providing copies of each document, certain foreign priority documents have not been considered given that they are in foreign languages (e.g., French, Japanese) and no translation nor an explanation of its contents have been provided. The Information Disclosure Statement fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 and the crossed-out information referred to therein has not been considered.

Applicant is invited to clarify the record concerning the submission of the documents either in the instant or parent applications.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

Applicant should update the status of the priority documents on page 1 of the instant specification.

Further, the following is noted.

An incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. See 35 USC 132(a). If an incorporation –by-reference statement is included in an amendment to the specification to add a benefit claim after the filing date of the application, the amendment would not be proper.

See Part VII of United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

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6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

7. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Applicant is required to amend the specification to comply with these guidelines.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(g) during the course of an interference conducted under action 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Rule 1.658(c)

(C) A judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a motion under § 1.633 (a) through (d) and (f) through (j) or § 1.634, and (3) could have been properly raised and decided in an additional interference with a motion under § 1.633(e). A losing party who could have properly moved, but failed to move, under § 1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with that party's failure to properly move, except that a losing party shall not be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment.

9. Claims 1-3 and 7-10 are rejected based on estoppel under Rule 1.658(c) for failure to take action during Interference 102,572 to place the subject matter of claims 1-3 and 7-10 in issue inter partes in an interference or for failure to move under 37 CFR Section 1.633(e) to have a second interference declared between applicant and Cabilly, Heyneker, Holmes, Riggs and Wetzel involving allegedly separately patentable subject matter.

See the Final Order in Patent Interference 102,572 and U.S. Patent No. 6,331,415.

On March 16, 2001, the Northern District of California (district court) entered an ORDER REGARDING RESOLUTION OF INTERFERENCE and a JUDGMENT. The district court determined "that Genentech is entitled as a matter of law to priority over Celltech to the invention described by the count". The district court's determination appears to have been based on a Cabilly draft application, dated February 1983.

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The Board of Interferences ordered that, consistent with the judgment of the district court, judgment on priority as to Count 1, the sole count in the interference, is now awarded against senior party, Boss, Kenten, Emtage and Wood (Celltech R&D, Ltd.)

U.S. Patent No. 6,331,415 discloses recombinant immunoglobulin molecules and recombinant immunoglobulins produced by yeast and bacterial cells encompassed by instant claims 1-3 and 7-10 (see entire document, including Summary of the Invention and Detailed Description of the Invention).

If claims 1-3 and 7-10 define an invention which is not separately patentable from the subject matter of the lost Count, the claims 1-3 and 7-10 are not patentable based on the proposition that a party losing an interference is not entitled to claim an invention which is not separately patentable from the lost count. See In re Deckler, 24 USPQ2d 1448 (Fed. Cir. 1992) (junior party losing interference to senior party based on senior party's foreign priority date is not entitled to claims to same patentable invention as count - - based on estoppel).

Deckler notes, 24 USPQ2d at 1449: interference judgment conclusively determined that, as between Deckler Grataloup was entitled to claim the patentable subject matter defined in the interference count in Interference 102,572. It is therefore proper and consistent with the policies of finality and repose embodied in the doctrines of res judicata and collateral estoppel, to use that judgment as a basis for rejection of claims the same patentable invention.

Also relevant is In re Kroekel, 231 USPQ 640 (Fed. Cir. 1986). Kroekel lost an interference to Comstock. After resumption of ex parte prosecution in the Kroekel application, Kroekel attempted, in claim 40, to claim subject matter described by Kroekel. The Federal Circuit held that Kroekel was estopped to claim the subject matter claim 40, because it had not been shown to be patentably distinct from the interference count.

If applicant asserts that the subject matter of claims 1-3 and 7-10 is not the same patentable invention as the lost Count in Interference 102,572, then applicant are not entitled to claims 1-3 and 7-10 based on their failure to move to put the subject matter of claims 1-3 and 7-10 in the interference (Interference 102,572) or in an additional interference.

Applicant is not entitled to pursue claims 1-3 and 7-10 post-interference. In other words, the estoppel provisions of Rule 1.658(c) preclude applicant from now seeking a patent to claims 1-3 and 7-10. Applicant's right to a patent containing claims 1-3 and 7-10 could have been properly raised and decided in Interference 102,572 or an additional interference. Applicant should have moved, but failed to move, to place the subject matter of claims 1-3 and 7-10 in issue inter partes, are now estopped pursuant to Rule 1.658(c) from seeking that subject matter in the instant application.

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Given the prosecution history of this family of applications and that Adair et al. (EP 0388 151 A1) is applied in the rejection under 35 USC 103(a) herein,

the following rejection of record in parent USSN 10/149,992 has been set forth to advance prosecution, even though the election of disease/disorder is different from the parent application.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by Adair et al. (EP 0388 151 A1) (1449) (see entire document).

Adair et al. teach methods of providing for modified antibodies for diagnostic and therapeutic procedures, including specificities for tumor antigens (e.g. page 4, paragraph 5) that have been produced with glycosylation sites in a variety of host cells including CHO cells (see entire document, including Summary of the Invention and the Description of Specific Embodiments of the Invention). Adair et al. teach the advantages of modifying the glycosylation of such antibodies includes modifying half-life, preserving properties such as activating complement, binding Fc receptors and inducing ADCC (see Background of the Invention on page 2; Summary of the Invention on pages 3-4 and Abstract).

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13. Claims 1, 2, and 7-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Adair et al. (EP 0388 151 A1) (1449) in view of Queen et al. (U.S. Patent No. 5,530,101) OR Waldmann et al. (U.S. Patent No. 5,846,534) (1449).

Adair et al. teach methods of providing for modified antibodies for diagnostic and therapeutic procedures, including specificities for tumor antigens (e.g. page 4, paragraph 5) that have been produced with glycosylation sites in a variety of host cells including CHO cells (See entire document, including Summary of the Invention and the Description of Specific Embodiments of the Invention). Adair et al. Teach the advantages of modifying the glycosylation of such antibodies includes modifying half-life, preserving properties such as activating complement, binding Fc receptors and inducing ADCC (see Background of the Invention on page 2; Summary of the Invention on pages 3-4 and Abstract). Construction of such chimeric or humanized antibodies involve recombinant expression vectors comprising the immunoglobulin heavy or light chain, introducing such vectors into CHO cells, culturing said cells, recovering said glycosylated antibodies and administering said antibodies (e.g. see Description of Specific Embodiments of the Invention).

Adair et al. differs from the claimed methods by not disclosing that the elected invention arthritis as the target of immunotherapy with CHO glycosylated antibodies.

Queen et al. teach methods of producing recombinant antibodies that can be readily produced and that are substantially less immunogenic for treating human disorders (see entire document, including Summary of the Invention and Detailed Description of the Invention), including the treatment of autoimmune diseases such as rheumatoid arthritis (e.g. see column 19, lines 19-26; column 21, paragraph 1; column 23, paragraph 2; column 26, paragraph 1; column 36, paragraphs 3-5). In addition, Queen et al. teach administering about 1 to about 200 mg of antibody per dose, with dosages of from 5 to 25 mg, including single and multiple administration depending on variables such as the severity of the disease and the patient, which would be determined the ordinary artisan, namely the treating physician at the time the invention was made (e.g. see columns 23-24).

Waldmann et al. teach recombinant antibodies, particularly antibodies to CAMPATH-1, to treat autoimmune diseases, including rheumatoid arthritis (see entire document, including Detailed description of the Invention, including Examples).

Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Queen et al. and Waldmann et al. to those of Adair et al. to obtain CHO glycosylated antibodies to treat autoimmune diseases such as arthritis.

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According to Adair et al., a person of ordinary skill in the art would have been motivated to produce CHO glycosylated therapeutic antibodies, given the advantages of ease and control of production of recombinant antibodies and the advantages of such modifications for altering antibody half-life and effector function(s) in human therapy.

Given providing effective amounts of therapeutic antibodies depended upon various parameters such as the nature of the disease and the patient and the desired endpoints associated with a particular disease/patient, the two-part dosing regime recited in claims 9-10 would have been obvious to the ordinary artisan in providing said effective amounts to a patient in need at the time the invention was made. The claimed dosages were well within the purview of effective amounts and the multiple administration of therapeutic antibodies, which would have comprised a two-part dosing regimen, particularly given the chronic nature of many diseases/disorders, including autoimmune diseases such as arthritis. Further, particular parameters such as dosages and modes of administration were well known and recognized as being result-effective variables (i.e., a variable which achieves a recognized result) in therapeutic regimens at the time the invention was made. In turn, the determination of the optimum or workable ranges of said variables might be characterized as routine experimentation. For example, MPEP 2144.05, including In re Antonie, 195 USPQ 6 (CCPA 1977).

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 1, 2 and 7-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 17, 18, 21-28, 30, 31, 37, 39 and 40 of copending USSN 10/145,992 in view of Mather et al. (U.S. Patent No. 5,122,469) (1449), Zettlemeissl et al. (Biotechnology 5: 720-725, 1987) (1449); Handa-Corrigan et al. (Enzyme Microb. Technol. 11: 230-235, 1989) and Schneider (J. Immunol. Methods 116: 65-77, 1989).

Given the election of species of treating autoimmunity / arthritis in the instant application and of the election of species of treating non-Hodgkin's lymphoma in the copending application USSN 10/145,992,

The claims drawn to species diseases / conditions (e.g. arthritis, lymphoma) of the instant and copending applications are not included in this provisional double patenting rejection.

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The instant claims as well as the patented claims either anticipate or render obvious one another, given that both are drawn to the same or nearly the same methods of treating patients suffering from diseases or disorders with therapeutic antibodies that have been glycosylated in a CHO expression system. Although the instant claims do not recite the particular serum free medium and pluronic acid of the instant claims, These modifications were obvious in view of the teachings of Mather et al. (U.S. Patent No. 5,122,469) (1449), Zettlemeissl et al. (Biotechnology 5: 720-725, 1987) (1449); Handa-Corrigan et al. (Enzyme Microb. Technol. 11: 230-235, 1989) and Schneider (J. Immunol. Methods 116: 65-77, 1989) for the reasons set forth in copending USSN 10/145,992. For example, the claimed inventions encompass the known steps of culturing transfected CHO cells in serum-free medium, including the known use of pluronic F68 as a cell protectant.

Mather et al. teach small scale and large scale production of applying methods of culturing CHO to high densities in order to improve production of recombinant proteins, including the use of serum free media and the ingredients recited in the instant claims, including the presence of pluronic F68 (see Preparation of Media, particularly column 10, paragraph 1; Tables 3 – 4 and Table A or Example 1; Claim 3) (see entire document, including Background of the Invention, see column 2; Summary of the Invention, column 3; Detailed Description of the Invention and Claims).

Handa-Corrigan et al. teach the use of defined serum-free media as well as the use of the cell protective agent pluronic F-68 in the growth of mammalian cells (See entire document, including Abstract, Results and Discussion and Conclusion).

Similarly Schneider discloses the optimization of hybridoma cell growth and antibody secretion in chemically defined serum-free culture media, including the use of pluronic F68 as well as Iscove's media (see entire document, including Abstract, Materials and Methods, Results and Discussion). Schneider teach that pluronic acid had no toxic effects on hybridoma cells, improved cell growth and increased antibody secretion (see Effect of Pluronic F68 on page 72). Schneider teach the use of a totally chemically defined medium for the cultivation of cells provides several advantages over the classical serum-containing media (e.g. see Conclusion, including page 76, column 1, paragraph 3).

Zellemeissl et al. teach the expression of biologically active recombinant protein in CHO cells, including the ability to achieve more than 30 splittings (see entire document, including page 721, column 1, paragraph 3).

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Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Maher et al., Handa-Corrigan et al. and Schneider to grow CHO cells expressing recombinant antibodies, given the advantages of chemically defined serum-free media and pluronic F68 in the growth of mammalian cells, including CHO cells and/or antibody producing cells, particularly for large-scale cultivation of such cells, as taught by the secondary references. The prior art chemically defined media taught by the secondary references teach the components recited in claims 24-27 (see citations above). Also, Zellemeissl et al. teach that CHO cells expressing and producing biologically active recombinant proteins could readily undergo a number of passages. Given these teachings of small scale and large scale production recombinant proteins in CHO cells over multiple passages, the ordinary artisan would have had both motivation and a reasonable expectation of success that CHO cells could be cultured for multiple passages, which could occur from two months to greater than five months.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. It would have obvious to one of ordinary skill in the art that the recitation of a CHO expression system in the copending claims would have included the advantages of a serum-free media and pluronic acid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
November 27, 2006

A handwritten signature in black ink, appearing to read "Phillip Gambel", with a long horizontal flourish extending to the right.